

**REMARKS**

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-26 are currently pending in this application, of which claim 1, 12, 19 and 22 are independent and the remainder dependent. Claims 1, 4, 12-13, 19 and 22 are currently amended. Claims 25-26 are newly added.

**SUMMARY OF EXAMINER INTERVIEW**

Initially, Applicants wish to thank Supervisory Patent Examiner Long Le and Examiner Nguyen for their time at the interview of June 2, 2010, the contents of which are summarized below.

Arguments with respect to the outstanding prior art rejections were discussed during the course of the interview. No agreement with respect to the claims was reached.

**REJECTIONS UNDER 35 U.S.C. § 102**

Claims 12 and 14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by US 6,556,695 Packer et al. ("Packer"). Applicants respectfully traverse this rejection for the reasons detailed below.

It is alleged in the Office Action at page 2 that Packer anticipates "at least one input interface for electroanatomical 3D mapping data and 3D image data," as recited in claim 12, in FIG. 1, col. 2, lines 14-60, col. 3, lines 51-67.

Fig. 1 of packer merely illustrates a MRI apparatus. Col. 3, lines 51-67 of Packer relate to the imaging modality for producing the high resolution model (CT, MRI, ultrasound). Col. 2, lines 14 -60 of Packer disclose acquiring image data of the subject anatomy and reconstructing an image which is a high resolution model of the subject anatomy; performing a medical procedure in which the subject anatomy

is imaged in real-time by acquiring low resolution images at a high frame rate; registering the high resolution model of the subject anatomy with each acquired low resolution image; and displaying images of the registered high resolution model of the anatomy.

As is understood, the cited sections of Packer do disclose or even suggest any “3D mapping data,” as recited in claim 12.

It is further alleged in the Office Action at Page 2 that Packer anticipates “a registration module,” as recited in claim 12, in FIG. 1, FIG. 8, col. 2, lines 14-60 and col. 9, line 21 - col. 10, line 36.

Fig. 8 shows a flowchart for producing a high resolution, large field of view images in real-time on the display, “overlying devices on image (242)” and an arrow from block 242 to the beginning. Col. 9, line 21 – col. 10, line 36, describes the flowchart (fig. 8), without referring to *any* electrophysiological data. The cited text passages or figures do not describe how electrophysiological data are merged with the anatomic model, especially fail to disclose or even suggest any “automatically [correlation of] the electroanatomical 3D mapping data and the 3D image data representing the 3D surface profile by surface matching of the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data in at least one stage of the registration, the automatic correlation carried out with correct position and dimension,” as recited in independent claim 12.

Packer in col. 12, line 35 – col. 13, line 15 discloses that the location of the electrodes is registered manually with the high resolution image. Without this manual registration, it would not be possible to assign the measured activation in form of a color modulation of the appropriate pixel. Accordingly, Packer fails to teach or fairly suggest any “automatic correlation.” Further, sensing electrical signals in Packer is not “3D mapping” as claimed, since the electrical signals produced by the electrodes of Packer (268, FIGS. 9-10) indicate the relative timing

of the signals during cardiac cycle. As such, they cannot be regarded as electroanatomical 3D mapping data, but only as voltage over time signals.

Additionally, the arrow from block 242 to the beginning (Fig. 8) does not mean that the high resolution model with the overlaid electrophysiological data is input to the registration procedure with the real-time image. The Examiner alleges that the high resolution image of Packer would contain the electrical activation map and the registration in block 236 could be regarded as registration of the mapping data with the real-time image. However, the arrow means that the displayed image is continuously updated, i.e. a new real-time image is registered with a newly selected high resolution image (according to the ECG phase) and this image is overlaid again with the electrophysiological data by modulation the pixel color. Therefore, Packer does not disclose an "automatic registration" of the 3D image data and electroanatomical 3D mapping data.

Still further, as admitted by the Examiner on Page 4 of the Office Action, Packer fails to disclose any "surface profile."

For at least all these reasons, Applicants submit that Packer fails to anticipate and/or render obvious each and every limitation of independent claim 12.

Claim 14, dependent on independent claim 12, is patentable for the reasons stated above with respect to claim 12 as well as for its own merits.

Applicants, therefore, respectfully request that the rejection to claims 12 and 14 under 35 U.S.C. § 102(b) be withdrawn.

**REJECTIONS UNDER 35 U.S.C. § 103**

**Packer/Rose**

Claims 1-3, 5, 8-9 and 19-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer and in view of US 2002/0176608 Rose ("Rose"). Applicants respectfully traverse this rejection for the reasons detailed below.

With respect to the rejection of claims 1, 19 and 22, Applicants respectfully incorporate the arguments presented above with respect to claim 12, and submit that, although each of claims 1, 19 and 22 should be construed solely based on the limitations contained therein, they are also allowable over Packer for the reasons given above with respect to independent claim 12.

Further, Applicants submit that Rose fails to teach or fairly suggest any "surface profiling" that is concerned with anatomy of living organisms. Rose is directed to surface-profiling of road surfaces. During the interview, the Examiner stated that Rose one of ordinary skills in the art would be motivated to incorporate the teachings regarding surface profiling in Rose in the Packer device and method.

However, there is no disclosure or suggestion in Packer and/or Rose to do so. A statement that modifications of the prior art to meet the claimed invention would have been within the skill of a person of ordinary skill in the art at the time of the invention is not sufficient to establish *prima facie* obviousness without some objective to do so (MPEP §2143.01). In the present case, the Examiner is using impermissible hindsight to reconstruct the elements of the claims. There is no objective reason one skill in the art at the time of the invention would seek to modify the elements of the reference and to do so would require such innovation as to be inventive. Additionally, Rose and Packer are directed to non-analogous subject matter.

Further, the teaching or suggestion to modify the reference and the reasonable expectation of success must both be found in the prior art, and not

based on Applicants disclosure (MPEP §2143). In making an assessment of the differences between the prior art and the claimed subject matter, 35 U.S.C. §103 specifically requires consideration of the claimed invention “as a whole.” The “as a whole” instruction in 35 U.S.C. §103 prevents evaluation of the invention on a part-by-part basis. Without this important requirement, an obviousness assessment might break an invention into its component parts, then find a prior art reference corresponding to each component. This line of reasoning improperly imports hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components (*Ruiz v. A.B. Chance Co.*, 357, F.3d 1270, 1275, (Fed. Cir. 2004)).

Applicants respectfully remind the Examiner that “[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

For at least all these reason, Applicants submit that the alleged combination of Packer and Rose is improper and therefore, each of claims 1, 19 and 22 is non-obvious to one of ordinary skill in the art.

Claims 2-3, 5, 8-9, 20-21 and 23-24, dependent on one of independent claims 1, 19 and 22, are patentable for the reasons stated above with respect to claims 1, 19 and 22 as well as for their own merits.

Applicants, therefore, respectfully request that the rejection to claims 1-3, 5, 8-9 and 19-24 under 35 U.S.C. § 103(a) be withdrawn.

#### Packer/Rose/Hemler

Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of “A System for Multimodality Image Fusion” Hemler et al. (“Hemler”) and further in view of DE 19953308 Williams et al

("Williams"). Applicants respectfully traverse this rejection for the reasons detailed below.

Hemler discloses a system for combining CT and MR images. Anatomical landmarks, such as bones, are segmented semi-automatically in both images, a transformation is determined and a registration measure is computed.

Williams discloses a registration method wherein fiducial markers [0037, 0038] are touched by a position sensor and the position of the markers with respect to the previously acquired image is ascertained by a computer in which the previously acquired image has been loaded. The touching of several markers enables image registration.

However, none of Packer, Hemler and Williams, alone or in combination, teach or fairly suggest the method of claim 4 comprising "registering, with the correct position and dimension, by automatically correlating in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and refining the registration obtained in the first stage by the surface matching in a later second stage." Namely, none of Packer, Hemler and Williams, alone or in combination, teach or fairly any multi-stage process as required by claim 4.

For at least all these reasons, Applicants submit that the alleged combination of Packer, Hemler and Williams fails to render the limitations of claim 4 obvious to one of ordinary skill in the art.

Applicants, therefore, respectfully request that the rejection to claim 4 under 35 U.S.C. § 103(a) be withdrawn.

Packer/Hemler/Williams

Claims 13 and 18 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer and in view of Hemler and further in view of Williams. Applicants respectfully traverse this rejection for the reasons detailed below.

Applicants respectfully incorporate the arguments above with respect to claim 4 and submit that the alleged combination of Packer, Hemler and Williams fails to render the limitations of claim 13 obvious to one of ordinary skill in the art because the alleged combination of Packer, Hemler and Williams fails to teach or fairly suggest the device of claim 13 wherein “the registration module automatically correlates in a **multi-stage process**, and the registration module registers, with the correct position and dimension, by automatically correlating in a first stage during the performance of the catheter application using at least one of distinct anatomical points and artificial markers and refines the registration obtained in the first stage by surface matching in a later second stage.”

Additionally, claims 13 and 18 are dependent on claim 12, and claim 12 is shown to be patentable over Packer above. Further, Hemler and Williams fail to overcome the noted deficiencies of Packer. Therefore, the alleged combination of Packer, Hemler and Williams fails to render the limitations of claims 13 and 18 obvious to one of ordinary skill in the art.

Applicants, therefore, respectfully request that the rejection to claims 13 and 18 under 35 U.S.C. § 103(a) be withdrawn.

Packer/Rose/Solomon

Claims 10-11 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of US 2003/0018251 Solomon et al. (“Solomon”). Applicants respectfully traverse this rejection for the reasons detailed below.

Claims 10-11 and 17 are dependent on claim 1, and claim 1 is shown to be patentable over Packer and Rose above. Further, Solomon fails to overcome the noted deficiencies of Packer and Rose. Therefore, the alleged combination of Packer, Rose and Solomon fails to render the limitations of claims 10-11 and 17 obvious to one of ordinary skill in the art.

Applicants, therefore, respectfully request that the rejection to claims 10-11 and 17 under 35 U.S.C. § 103(a) be withdrawn.

Packer/Solomon

Claims 15-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Solomon. Applicants respectfully traverse this rejection for the reasons detailed below.

Claims 15-16 are dependent on claim 12, and claim 12 is shown to be patentable over Packer above. Further, Solomon fails to overcome the noted deficiencies of Packer. Therefore, the alleged combination of Packer and Solomon fails to render the limitations of claims 15-16 obvious to one of ordinary skill in the art.

Applicants, therefore, respectfully request that the rejection to claims 15-16 under 35 U.S.C. § 103(a) be withdrawn.

Packer/Rose/Massaro

Claim 6 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of US 2002/0087329 Massaro ("Massaro"). Applicants respectfully traverse this rejection for the reasons detailed below.

Claim 6 is dependent on claim 1, and claim 1 is shown to be patentable over Packer and Rose above. Further, Massaro fails to overcome the noted deficiencies of



Packer and Rose. Therefore, the alleged combination of Packer, Rose and Massaro fails to render the limitations of claim 6 obvious to one of ordinary skill in the art.

Applicants, therefore, respectfully request that the rejection to claim 6 under 35 U.S.C. § 103(a) be withdrawn.

Packer/Rose/Shoji/Chiu

Claim 7 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Rose and further in view of US 6,572,476 Shoji et al. ("Shoji") and further in view of US 2004/0233217 Chiu et al. ("Chiu"). Applicants respectfully traverse this rejection for the reasons detailed below.

Claim 7 is dependent on claim 1, and claim 1 is shown to be patentable over Packer and Rose above. Further, Shoji and Cho fail to overcome the noted deficiencies of Packer and Rose. Therefore, the alleged combination of Packer, Rose, Shoji and Cho fails to render the limitations of claim 7 obvious to one of ordinary skill in the art.

Applicants, therefore, respectfully request that the rejection to claim 7 under 35 U.S.C. § 103(a) be withdrawn.

**NEW CLAIMS**

Claims 25-26, reciting subject matter somewhat similar to claims 4 and 13, respectively, are newly added and also patentable over the prior art at least for the reasons given above with respect to corresponding independent claims 19 and 22 and also on their own merits.

**CONCLUSION**

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.


Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Donald J. Daley at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By

  
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